THREE -YEAR EXPERIENCE WITH THE ULTRACOR VALVE PROSTHESIS

A. TAŞDELEN, M.D.,
C. İKİZLER M.D.,
S. AŞLAMACI, M.D.,
A. YAVARİ, M.D.,
E. EKİCİ, M.D.,
G. ARSLAN, M.D.

From: Department of Cardiovascular Surgery, Başkent University Hospital, Bahçelievler, Ankara, Türkiye

Adress for reprints:
A.TAŞDELEN, M.D., Başkent University Hospital, Department of Cardiovascular Surgery, Bahçelievler, 06490 Ankara, TÜRKİYE

From February 1992 until October 1995, 504 patients, 3 to 69 years of age (median = 36) received 663 Ultracor Prosthesis (103 aortic, 259 mitral, 12 tricuspid and 130 multiple). Overall early mortality was 2.76%, within 0.79%, 1.78% and 0.19% after aortic, mitral and multiple valve replacement respectively. Follow-up was 100% (719.5 patients years). Overall mortality (including both early and late deaths) was 0.99% after aortic valve replacement, 1.98% after mitral valve replacement, 0.19% after tricuspid valve replacement and 0.59%aftermultiple valve replacement.

All patients including 33 children (3.5 to 18 years of age) received sodium warfarin. The linearized risk per patient years for all embolic events (major and minor) was 0.69, 1.11 and 0.69 after aortic, mitral and multiple valve replacement, respectively. When only major events were considered, the linearized risk were 0.27,0.13 and 0 respectively. Freedom from major systemic embolism was 99%±0.07 after aortic valve replacement, 99%±0.07 after mitral valve replacement and 99%±0.06 after multiple valve replacement. 7 patients had valve thrombosis, 6 of whom definitely received inadequate anticoagulation therapy. 12 patients had 25 episodes of anticoagulant-related hemorrhage. To reduce the rate of thromboembolism without increasing the rate of anticoagulant-related hemorrhage, we proposed that the international normalized ratio should be kept between 2 and 2.5.

No recorded structural failure or significant hemolysis was found in the absence of periprosthetic leak. This experience encourages us to continue using the Ultracor Prosthesis.

Key words: Heart valve replacement, cardiac valve prosthesis, prosthetic valve related complications

Although heart valve replacement is a safe and commonly performed procedure, all available prosthesis are associated with valve-related complications that influence their clinical use. With the introduction of each new prosthetic valve, it behaves surgeons and cardiologists to monitor it's performance carefully, and reasonable attempts can be made to compare prosthesis with each other.

We introduced the Ultracor Prosthesis into our clinic in February 1992 (Aortech Europe Ltd., Sbtrathclyde Business Park, Bellshill Stratclyde Scotland, UK).

What interested us in this particular prosthesis were mechanical features suggesting the possibility of a better hemodynamic performance: a 73 degrees opening angle in the aortic, 68 degrees in the mitral gives a large, effective orifice area. The wide disc movement would facilitate flow through the prosthesis, thus allowing reduction in the rate of thromboembolism. The orifice ring is machined from a solid block of grade A-70 pure titanium, eliminating welds. Flow impending structures are eliminated in the lesser orifice by the single strut design. Increased laminar blood flow results from the central location of the disk pivot axis. The prosthesis can be rotated in the knitted Teflon sewing cuff.

The purpose of this study was to analyze our clinical results with the Ultracor valve prosthesis in patients who were followed up 3 months to 3 years postoperatively, and here in record a 3 year follow up is presented. The preoperative, operative and postoperative clinical results will be reviewed.

PATIENTS AND METHODS

Patient characteristics: From the patient cohort in which the Ultracor heart valve prosthesis was implanted, the age dissociation was as following. The youngest patient was three (3) years of age, and the oldest patient was sixty nine (69). Mean patient age in this study was thirty nine(39). Patients who underwent double valve replacement in which the second valve was not an Ultracor prosthesis were excluded from the study. Follow-up data were obtained during 3-month intervals between February 1992 and October 1995.

Five hundred four patients received 663 Ultracor heart valves.

207 were male (41%) and 297 were female (59%). Most of the patients were in New York Heart Associated Class III and IV preoperatively. Operative techniques included standart cardiopulmonary bypass with a disposable bubble or hollow fiber membrane oxygenator, and moderate hypothermia (26°C to 30°C). Cold Crystalloid cardioplegia and topical cooling was used for myocardial protection. Cardiopulmonary bypass was established using ascending aortic and bicaval cannulation, employing systemic hypothermia and hemodilution. After meticulous debridement of the valve annulus, all of the prosthesis were inserted using interrupted sutures of 2-0 Ethibond (Eticon Somerwille NI), and teflon pledges were used when needed in the aortic position 2-0 Ethibond suture material and continuous suture technique were used in the mitral position. In tricuspid position 5 or 6,2-0 braided interrupted pledged sutures and continious suture technique were used. Valve sizes ranged from 19 to 33 mm. In high pulmonary hypertensive cases continious infusion of nitroglycerin through transventricular pulmonary artery catheter was infused.

This infusion was continued in the first days of postoperative period. At the same time monitorization of pulmonary artery pressure was measured.

Sodium warfarin therapy was started either 48 hours after operation or as soon as the chest drains were removed unless clinical contraindication existed. We attempted to maintain the prothrombin time at approximately twice normal control in mitral valve or multiple valve replacements. In aortic valve replacements the prothrombin time was maintained at 1-1/2 times normal.

Antibiotic prophylaxis consisted of penicillin procaine (800.000 UI). Penicillin-G (1.000.000 ÜI) and amikacin sulfate (500 mg) was administered preoperatively and 5 days postoperatively.

Distal coronary anastomasis were performed before replacing the mitral valve, thus decreasing the risk of myocardial rupture. In the majority of patients i.e. 446 patients or 88.5%, the diagnosis of rheumatic valve disease inconjunction with the clinical symptomatology made the implant of a heart valve prosthesis necessary. Congenital deformations of the natural valve led in 24

patients or 4.7% to replacement.In 11 patients (2.2%) ischemic heart disease was the cause of mitral insufficiancy. The remainder of patients suffered from degenerative disease i.e.23 patients or 4.6% (Table 1).

Valve Distribution

Single valve replacement was performed in a total of 374 patients. In 259 patients Ultracor valve was implanted in the mitral position (69.2%); for the aortic and tricuspid positions these numbers were 103 (27.5%) and 12 (3.2%) respectively.

Multivalve replacement:

Multivalve replacement was performed in a total of 130 patients, or 25.7% of the total patient cohort. In the majority of these patients, 96 (73.8%) double implant was performed in aortic and mitral position. Mitral and tricuspid replacement was done in 4 patients (3%) and aortic valve replacement in combination with a tricuspid implant in 1 case (0.7%). Finally triple valve replacement (aorta, mitral and tricuspid) was performed in 9 patients (6.9%).

Combined Surgical Procedures

Valve replacements in combination with coronary bypass surgery (CABG) was done in a total of 31 patients (6.1%). CABG procedure in conjunction with mitral valve replacement was performed in 16 (51.6%) patients, while in 11 (35.4%) of these the CABG procedure was done together with aortic valve replacement. For CABG combined with double or triple valve replacement the number of patients were 3 (9.6%) and 1 (3.2%) respectively (Table I-II).

Table I. Valvular pathology

Type	Patient No	%
Rheumatic	446	88.5
Congenital	24	4.7
Ischemic	11	2.2
Degenerative	23	4.6

Table II. Combined Surgical Procedures

Type	No	%
MVR +CABG	16	3.17
AVR +CABG	11	2.18
AVR +MVR +CABG	3	0.59
AVR +MVR +TVR +CABG	1	0.01
Total	31	5.95

CLINICAL RESULTS

Overall mortality:

A total of 19 patients died in the study. Early mortality accounted for 14 of these patients (2.77%) of the total patient cohort. Late mortality accounted for 5 of these patients (0.99%). Two of the cases of late mortality had to be attributed to the prosthesis, resulting in a valve related mortality of 0.4% (Table V).

Mortality in MVR:

From the group of patients on whom mitral valve replacement was performed i.e. 259 patients, a total of 10 died (3.85%). Early mortality accounted here for 9 patients (3.47%) and late mortality accounted for 1 patient (0.38%).

Mortality in AVR:

The total in the aortic valve replacement group i.e. 103 patients, was 5 patients (4.8%). Early mortality accounted here for 4 patients (3.8%) and late mortality accounted for 1 patient (0.97%) as well.

Mortality in TVR:

From the group of patients on whom tricuspid valve replacement was performed, i.e. 12 patients, 1 late mortality was observed (8.3%).

Mortality in double valve replacements:

From the total group who underwent double valve replacement i.e. 101 patients, 3(2.97%) died. Early mortality accounted for 1 (0.99%) and late mortality accounted for 2 patients (1.98%).

Mortality in triple valve replacements:

From the group of patients on whom triple valve replacement was performed i.e. 29 patients, no mortality was observed.

Mortality in CABG and valve replacement group (total of 31 patients) was 2 patients in early period (6.4%).

Causes of mortality:
A number of 5 patients died from myocardial dysfunction, 4 patients from prosthetic endocarditis, 4 patients from anticoagulant related hemorrhage, 6 patients malignant arrythmia, 1 patient from a myocardial rupture and 1 patient from neurologic insult. There is no mortality from thromboembolic complications (Table III).

COMPLICATIONS

In a total of 50 patients or 9.9% of the total patient cohort, complications were observed during this study. These complications are listed below (Table IV)

1. In 8 of the patients a paravalvular leak was seen (1.58%). 2 patients had a paravalvular leak after AVR, 6 patients suffered a paravalvular leak after MVR. Reoperation was performed in all patients. 5 patients had had fever but negative blood cultures in the initial postoperative period. 2 patients had annular dehiscence several months after discharge from the hospital; the dehiscence probably due to the poor quality of the annular tissue. The remaining patients will shortly undergo reoperation. The linearized incidence was 0.33% patient year.

2. One patient (0.19%) suffered from sternal dehiscence.

3. Thromboembolism was seen in 8 patients (1.58%). Two of these events resulted in rethinopathy, which diagnosis was confirmed by CT. The third patient suffered from a sudden occlusion of the superior mesenteric artery. Partial resection of the jejenum was performed. All three patients are alive and are doing well. The other embolic events were: 2 arterial embolism in the lower extremity, and 4 cerebral emboli. There was no mortality because of thromboembolism.

4. One patient (0.19%) was reoperated for hemorrhage in early postoperative period (Cardiac tamponade).

5. In 5 patients prosthetic valve thrombosis (0.9%) was observed. The 3 patients underwent MVR and 2 patients TVR surgery. Prothrombin time levels in all three patients

Table III. Causes of Mortality

	No	%
A. Valvular		
prosthetic valve endocarditis	4	0.79
B. Nonvalvular		
Cerebral hemorrhage	2	0.39
Myocardial dysfunction	5	0.99
Malignant arrhythmia	6	1.19
Myocardial rupture	1	0.19
Neurologic insult	1	0.19
Total	19	3.75

Table IV. Complications.

	No	%
Paravalvular leak	8	1.58
Thromboembolism	8	1.58
Sternal dehiscence	1	0.19
Tamponade	1	0.19
Prosthetic valve thrombosis	5	0.99
Pannus related valve dysfunction	5	0.99
Anticoagulant related hemorrhagia	16	3.17
Valve endocarditis	6	1.11
Total	50	9.9

Table V. Mortality Rates

Replacement Type	Early	Late	Overall
MVR	3.47	0.38	3.85
AVR	3.8	0.97	4.8
MVR + AVR	0.99	1.98	2.97
AVR+MVR+TVR	0	0	0
Overall	2.77	0.99	3.7

were very low, as a result of misunder standing the prescribed anticoagulant therapy (sodium warfarin). The first patient was operated on August, 1992 and reoperation was performed one year later. The 25 mm mitral valve was replaced by a same type and size of the valve. The patient is doing well. The second patient was operated on June, 1993. A 25 mm mitral Ultracor valve was implanted, replacing a 25 mm Carbomedics. Upon discharge the patient stopped taking the warfarin, as prescribed. On February, 1994, she was admitted to hospital in deep circulatory collapse, Emergency surgery was performed successfully, by replacing the mitral valve with a 25 mm Ultracor prosthesis. The patient is currently doing well, but she is still opposed to accept anticoagulant therapy. In the third patient who was implanted an Ultracor valve in the tricuspid position on December, 1993, a tricuspid valve reimplantation was done on February, 1994. The reason for reoperation was an intermittent disk impingement, probably related to suboptimal positioning of the prosthesis during the first implant. The patient is doing well. The other two patients were operated successfully and a Ultracor valve prosthesis was replaced by the same type and size. They are doing well.

6. In 5 patients (0.9%) valvular dysfunction was noted related to pannus formation. The first patient had the mitral valve rereplacement after one year, the other in whom double valve replacement (MVR+ TVR) had been performed; mitral valve was replacement after two years. The other 3 patients had the mitral valve replaced after one, three and four years respectively. All the patients are doing well. Inspection of the pannus tissue revealed that the tissue did not result from ingrowth but rather from healed minor infection.

7.Anticoagulant related hemorrhage was seen in 16 patients (3.17%). In two of these cerebral hemorrhage developed leading to exitus. In 8 patients minor symptoms of haematuria were observed. These patients are doing well. 6 patients showed minor symptoms of hemorrhagia and are also doing well at the moment.

8. Prosthetic valve endocarditis was observed in 6 patients (1.1%). Four of these patients died as a result of the infection and account entirely for the valve related mortality of the patient cohort.
The other patients were successfully treated and are doing well.

COMMENT

Webegan first using the Ultracor valve in 1992, its design offered the possibility of improved hemodynamic performance and perhaps a decrease in the rate of thromboembolic complications.
We are now able to examine our three year experience with this valve, but we have not enough time to report long term survival and to compare the results with other series. According to our three year experience we have no objective hemodynamic data available from this serie.
Thromboembolism is the major complication after prosthetic valve replacement. According to Nakano's series [5] the linearized rate of thromboembolism for AVR, MVR and DVR was 1.35% 1.63% and 0.79% per patient year respectively.
Akins[6] reviewed the performance chracteristics and complications of four mechanical valves approved by FDA for use in United States. For the St. Jude Medical valve the composite linearized rate of thromboembolism, calculated from the available data in 4823 patients, was 1.6% per patient year (range 0.7% to 2.8%) for AVR alone, it was 2.4% per patient year (range 0.4% to 4%) for MVR alone.
Our results are consistent with or show a lower incidence than these reports.
The rate of thromboembolic complications in our series (AVR, 0.69% patient year) is still comparing favorably with the other series (Arom[1]: AVR 1.1%, MVR 1.8%; Czer[2]: AVR 2.5%, MVR 1.6%; Kratz[3]: AVR 1.8%, MVR 2.9%). These thromboembolic rates also compare favorably with those reported by Daenen[4] for AVR with ball valve prosthesis (2.8%), tilting disc prosthesis (2.5%) and porcine prosthesis (3.8%) as well as for MVR

with ball valve prosthesis (3.2%), tilting disc prosthesis (3.5%) and porcine prosthesis (3.8%).

The fact that the Ultracor prosthesis has an almost central flow aims us to believe that the incidence of thromboembolism would be reduced. In our series, the incidence has been low and comparable with the best results reported.

Finally, the low incidents of thromboembolism in multiple valve is intriguing, as it would seem to be counterintuitive; that is, the population with a greater amount of prosthetic material ought to be at greater risk.

The incidence of anticoagulant related hemorrhage has decreased to 3.17% from our earlier series with other mechanical prosthesis (Björk-Shiley, Carbomedics). We have gradually decreased the level of anticoagulation to approximately twice normal control for MVR and multiple valve replacement and 1 1/2 times for AVR.

Although occasional reports of structural failure of the St. Jude valve have appeared, to our knowledge, none of our 504 patient has sustained this complication.

The incidence of prosthetic valve endocarditis is similar to that of Czer[2], Arom[1] and Kratz[3] is quite low (1.1%). Low incidence is presumably due to the cloth sewing ring has undergone complete tissue and is protected from bacterial invasion.

Operative mortality may be more strongly influenced by preoperative patient characteristics and operational principles (myocardial protection, operative techniques, fighting with pulmonary hypertension etc.) than by valve performance. Our overall operative mortality (AVR 0.79%, MVR 1.78%) compares favorably with that reported by Arom (AVR 5.2%, MVR 11.9%) and Kratz (AVR 3.9%, MVR 3.5%). Multiple valve results are favorable different with others (0.59%).

Most deaths in this serie were not from prosthesis related causes, which constituted 79% of deaths: indeed 99.21% of patients remained free of valve related causes of death after 3 years (Table III). The strongest risk factor for death was the presence and extent of associated coronary artery disease. Other independent risk factors for death is advanced age (greater than 70 years), advanced preoperative NYHA function Class (III or IV), and the presence of malignant ventricular ectopic beats. Reported series without a large proportion of high-risk patients may be expected to have a lower operative mortality and high survival rate [7-9].

The functional status of surviving recipients of the Ultracor valve was favorable when compared with the status before the operation. Whereas 80.6% were in Class III or Class IV preoperatively; 96.04% achieved class I or II by 6 months postoperatively. Furthermore, the profile did not change significantly at 1 year or 3 years after operation.

Long term survival is related to both underlying cardiac function, and age as well as to valve performance. We have no objective hemodynamic data available from this series. However, a large proportion (46.6/103) of our AVR patients received small (19 or 21) size prostheses and the significant, sustained and functional improvement was noted.

In our opinion, mechanical valves are great advance in valve replacement therapy. Though not yet perfect, they provide satisfactory results. In our experience the Ultracor valve has proven to be reliable prosthesis. The result of our analysis encourage us to continue using the Ultracor prosthesis with its proven excellent hemodynamics and absence of structural failure over 3 years. One of the major advantages of this valve is its low profile, which makes it especially useful in children and adults with small ventricles, particularly women. No structural failures have occured with these devices. Their durability and wide occluder movement favor fine hemodynamic performance, and at the same time, they have one of the lowest thromboembolic rates described in the literature.

In summary this series of patients undergoing isolated AVR and MVR and multiple valve replacement with Ultracor prosthesis confirms the excellent performance of this valve in our early results. Accordingly, it remains our prosthesis of choice when mechanical valve is needed.

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